SIEMENS

510(k) Summary: Mobilett Mira

SEP 19 2011

Company: Siemens Medical Systems, Inc.
1 Valley Stream Parkway
Malvern, PA 19355

Date Prepared: June 30, 2011

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. **General Information:**

Importer / Distributor:
Siemens Medical Solutions, Inc.
51 Valley Stream Parkway, E-50
Malvern, PA 19355
Establishment Registration Number:
2240869

Manufacturing Site:
Siemens S.A.
Parque Empresarial La Carpetana,
Avenida Leonardo da Vinci, 15
E-28906 Getafe (Madrid), Spain
Headquarters:
Siemens AG
Wittelsbacherplatz 2
D-80333 Munich 2, Germany
Establishment Registration Number:
1000342169

2. **Contact Person:**
Ms. Patricia D Jones
Technical Specialist, Regulatory Submissions
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway G-01
Malvern, PA 19355
Phone: (610) 448 -3536 Fax: (610) 448-1787
Email: patricia.d.jones@siemens.com

3. **Device Name and Classification:**

Trade Name:	Mobilett Mira
Classification Name:	Mobile X-ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1720
Device Class:	Class II
Product Code:	IZL

4. **Device Description:**

The Mobilett Mira is a mobile X-ray system with a solid state detector. The system is designed to provide X-ray imaging for healthcare professionals. Cable less operation and motor-driven movements are supported with build in rechargeable batteries. The mobile generator is positioned at bedside and the X-ray system is directed to the anatomical area to be imaged. The image detector is placed perpendicular to the central beam behind the anatomical area of interest. The system features a collimator with a light field that mimics the x-ray field to limit the field of exposure to the area to be imaged. Exposure may be released via remote control. The image data acquired by the detector are sent wireless to the mobile unit.

The Mobilett Mira is a modification of the Mobilett XP originally cleared under Premarket Notification K033238 on 11/14/2003. The modification consists of a rotatable suspension arm, a solid state image detector, digital image acquisition system and a 35KW generator. This modified Mobilett XP will be marketed under the trade name Mobilett Mira. The modification does not affect the intended use of the device nor does it alter its fundamental scientific technology.

5. **Intended Use:**

The Mobilett Mira is a radiographic system designed for use in wards, intensive care and premature-birth wards, pediatric and emergency departments, operating theatres as well as the central X-ray department.

6. **Substantial Equivalence:**

The Mobilett Mira is substantially equivalent to the following devices:

Predicate Device Name and Manufacturer	510(k) Number	Clearance Date	Comparable Properties
Mobilett XP Mobilett XP hybrid	K033238	11/14/2003	• Indications for use • X-ray Generator • X-ray tube
Ysio	K081722	08/22/2008	• Solid State detector • Imaging system

7. **Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device:**
The modified Mobilett XP will be marketed under the trade name Mobilett Mira. The modifications consist of a rotatable suspension arm, a solid state image detector, digital image acquisition system and a 35KW generator. These modifications are 510(k)cleared in the mentioned predicate devices. Several of the components used in the Mobilett Mira are either commercially available with current Siemens systems or include minor modifications to existing components.

8. **General Safety and Effectiveness Concerns:**
Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner. Several safety features including visual and audible warnings are incorporated into the system design. In addition the Mobilett Mira is continually monitored, and if an error occurs, the system functions will be blocked and an error message will be displayed.

   Furthermore the operators are health care professionals familiar with and responsible for the X-ray examinations to be performed. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing.

9. **Conclusion as to Substantial Equivalence:**
The Mobilett Mira is intended for the same indications for use as the predicate Mobilett XP / XP hybrid. The solid state imaging detector replaces the conventional cassette with film/screen combination. The portfolio of accessories is the same as with the predicate Mobilett XP. It is Siemens opinion, that the Mobilett Mira is substantially equivalent to the Mobilett XP.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Patricia D. Jones
Technical Specialist, Regulatory Submissions
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway, E-50
MALVERN PA 19355

SEP 19 2011

Re: K111912
Trade/Device Name: Mobilett Mira
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL
Dated: August 29, 2011
Received: August 30, 2011

Dear Ms. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K111912

Indications for Use Form

510(k) Number (if known): K111912

Device Name: Mobilett Mira

Indications for Use:

The Mobilett Mira is a radiographic system designed for use in wards, intensive care and premature-birth wards, pediatric and emergency departments, operating theatres as well as the central X-ray department.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

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